

**IN THE UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF VIRGINIA
ABINGDON DIVISION**

UNITED STATES OF AMERICA

v.

MEMORANDUM ORDER
Case No. 1:19cr00016

**INDIVIOR INC. (a/k/a Reckitt Benckiser
Pharmaceuticals Inc.) and
INDIVIOR PLC,
Defendants**

This matter is before the court on the Defendants’ Motion For Issuance Of Pre-Trial Rule 17(c) Subpoenas, (Docket Item No. 229) (“Motion”), the United States’ Response In Opposition To Indivior’s Motion For Issuance Of Pre-Trial Rule 17(c) Subpoenas, (Docket Item No. 242) (“Response”), and Defendants’ Reply In Support Of Motion For Issuance of Pre-Trial Rule 17(c) Subpoenas, (Docket Item No. 244). Based on the arguments and representations of counsel contained in the Motion and Response, and for the reasons set out below, the Motion is **GRANTED in part and DENIED in part**.

By Superseding Indictment returned August 14, 2019, the defendants, Indivior Inc. and Indivior LLC, (collectively, “Indivior”), are charged with conspiracy to commit mail, wire and health care fraud, health care fraud, four counts of mail fraud and 22 counts of wire fraud. In particular, the Superseding Indictment charges that Indivior executed a nationwide scheme to increase Suboxone Film prescriptions by deceiving health care providers and health care benefit programs into believing that Suboxone Film is safer and less susceptible to diversion and abuse than other similar drugs and by marketing Suboxone Film to health care providers

to be prescribed and dispensed in a careless and clinically unwarranted manner. The case is set for trial beginning May 11, 2020.

The Motion requests the court, pursuant to Federal Rules of Criminal Procedure Rule 17(c) to issue 11 subpoenas for the pretrial production of certain documents from five federal agencies and six state agencies. (Docket Item Nos. 230-1 to 230-11) (collectively “Subpoenas”). The Subpoenas seek production of some of the same information sought from the Government by the Defendants’ Motion To Compel, (Docket Item No. 117), which has been denied by the undersigned and is before the district judge on Indivior’s objections. (Docket Item No 226.)

Rule 17(c) simply allows a district court to issue a subpoena ordering a “witness to produce ... designated items in court before trial....” FED. R. CRIM. P. 17(c) (2019 Rev. Ed.) The rule, itself, sets no standard for the issuance of such a subpoena. The Supreme Court, however, in *United States v. Nixon*, 418 U.S. 683, 700 (1974), held that a moving party must show relevancy, admissibility and specificity in order to require production of a designated item prior to trial. The Court recognized that subpoenas duces tecum in criminal cases were not intended to provide a means of discovery, but, rather, were designed to expedite the trial by requiring the pretrial production and inspection of the subpoenaed materials. *See Nixon*, 418 U.S. at 698-99.

Based on the court’s review of the Subpoenas, the Superseding Indictment and the arguments and representations of counsel, the court finds that Indivior has met the relevancy, admissibility and specificity requirements of *Nixon* regarding the following Subpoenas:

1. Subpoena directed to the Substance Abuse and Mental Health Services Administration, (“SAMHSA”), for the following:
 - a. The records reflecting SAMHSA’s analysis leading to the conclusion incorporated in the “Clinical Guidelines for the Use of Buprenorphine in the Treatment of Opioid Addiction: A Treatment Improvement Protocol TIP 40” published to the SAMHSA website that buprenorphine dosing at amounts up to 32 mg per day is recommended for certain patients and the time period during which this guidance was available on SAMHSA’s website;
 - b. The records reflecting SAMHSA’s analysis leading to the conclusion published on SAMHSA’s website until at least 2017 in the publication titled, “Medication-Assisted Treatment for Opioid Addiction in Opioid Treatment Programs: A Treatment Improvement Protocol TIP 43” that while most buprenorphine “patients are likely to remain stable on 12 to 24 mg per day, ... some might need dosages of up to 32 mg per day” and the time period during which this guidance was available on SAMHSA’s website; and
 - c. The records reflecting SAMHSA’s analysis leading to the statement published as a part of its “Federal Guidelines for Opioid Treatment Programs” in 2015 that “[u]nless clinically indicated, there should be no limits on patients’ duration of treatment or dosage level of medication” and the time period during which this guidance has been available on SAMHSA’s website;
2. Subpoena directed to the Food and Drug Administration, (“FDA”), for the following:
 - a. The records reflecting the FDA Office of Prescription Drug Promotion’s, formerly known as the Division of Drug Marketing, Advertising and Communications, receipt and review of the following promotional or marketing materials for Suboxone Film submitted by Reckitt Benckiser Pharmaceuticals Inc., (“RBPI”), or Indivior Inc. between 2010 and 2019:
 - i. Any submissions referencing Suboxone Film “Helping Address Public Health Needs;”

- ii. Any submissions stating that Suboxone Film could “Help Address Misuse and Abuse;”
 - iii. Any submissions stating that Suboxone Film “Can Be Part of the Solution” to “misuse,” “diversion and abuse,” and “unintentional pediatric exposure;”
 - iv. Any submissions stating that “Nearly half of Suboxone Film prescribers surveyed cited ‘potential for reduction of abuse and diversion’ as a reason to prescribe vs Suboxone Tablet;”
 - v. Any submissions including a chart with the heading, “Suboxone Film—Helping to Reduce the Risk of Pediatric Exposure;”
 - vi. Any submissions including a chart with the heading, “Suboxone . . . Film — associated with lower rates of diversion and abuse . . .;” and
 - vii. Any submissions referencing data showing “fewer pediatric exposures for Suboxone Film vs Suboxone Tablet;”
- b. The records reflecting the analysis and review underlying the conclusion reached by the FDA’s Office of Surveillance and Epidemiology, as expressed and reviewed by Kellie Taylor and Gerald Dal Pan in connection with the office’s assessment of the 2012 Reckitt Benckiser Pharmaceuticals Inc. Citizen Petition, that “Suboxone film in unit-dose packaging poses a lower overall risk of accidental pediatric exposure than Suboxone tablets in multi-dose packaging” and that “the role of unit-dose packaging and child-resistant closures are well accepted measures of preventing accidental pediatric exposures to drug products.” This will include all underlying data reviewed in assessing the comparative pediatric exposure risk;
- c. The records reflecting the analysis and review underlying the conclusion reached by the FDA’s Division of Anesthesia, Analgesia, and Addiction Products, as expressed and reviewed by Celia Winchell, Rigoberto Roca, and Bob Rappaport in connection with the division’s assessment of the 2012 Reckitt Benckiser Pharmaceuticals Inc. Citizen Petition, that “Suboxone film in unit-dose packaging poses a lower overall risk of accidental pediatric exposure than Suboxone tablets in multi-dose packaging.” This will include all underlying data reviewed in assessing the comparative pediatric exposure risk;

- d. The records reflecting the analysis and review underlying the conclusion reached by the FDA's Division of Medication Error Prevention and Analysis, as expressed and reviewed by Kellie Taylor, Sue Liu, and Carol Holquist in connection with the division's assessment of the 2012 Reckitt Benckiser Pharmaceuticals Inc. Citizen Petition, that "Suboxone film in unit-dose packaging poses a lower overall risk of accidental pediatric exposure than Suboxone tablets in multi-dose packaging." This will include any underlying data reviewed in assessing the comparative pediatric exposure risk;
- e. The records reflecting the analysis and review underlying the conclusion reached by the FDA's Division of Epidemiology, as expressed and reviewed by Christian Hampp in connection with the division's assessment of the 2012 Reckitt Benckiser Pharmaceuticals Inc. Citizen Petition, that "Suboxone film in unit-dose packaging poses a lower overall risk of accidental pediatric exposure than Suboxone tablets in multi-dose packaging" and that "if there is a return to market dominance of buprenorphine/naloxone tablets without unit-of use packaging, pediatric exposures are likely to rise." This will include any underlying data reviewed in assessing the comparative pediatric exposure risk;
- f. The records reflecting the guidance provided to generic buprenorphine manufacturers regarding the FDA's classification of the packaging of buprenorphine-containing products as a "significant safety issue in regards to pediatric exposure," including the FDA's recommendation to switch to unit-dose packaging for buprenorphine-containing products. This will include, but not be limited to, the documents reflecting the communications or analysis conducted in advance of and in connection with the guidance provided to generic buprenorphine manufacturers during the April 9, 2013, meeting of the Buprenorphine Product Manufacturers Group on the BTOD REMS Submission; and
- g. The records reflecting the FDA review or analysis of the dosage amounts included in the approved labels for Suboxone Tablet and Suboxone Film; and

3. Subpoena directed to the Centers for Disease Control and Prevention, (“CDC”), for the following:
 - a. The records reflecting the analysis of and views expressed by Daniel S. Budnitz, MD, within the CDC’s Division of Healthcare Quality Promotion, regarding the impact of unit-dose packaging of buprenorphine products on pediatric exposure and the findings addressed in the October 21, 2016 publication titled, “Pediatric Emergency Department Visits for Buprenorphine/Naloxone Ingestion – United States, 2008-2015;”
 - b. The records reflecting the analysis of and views expressed by Maribeth C. Lovegrove, MPH, within the CDC’s Division of Healthcare Quality Promotion, regarding the impact of unit-dose packaging of buprenorphine products on pediatric exposure and the findings addressed in the October 21, 2016, publication titled, “Pediatric Emergency Department Visits for Buprenorphine/Naloxone Ingestion – United States, 2008-2015;”
 - c. The records reflecting the analysis of and views expressed by Mathew R.P. Sapiano, PhD, within the CDC’s Division of Healthcare Quality Promotion, regarding the impact of unit-dose packaging of buprenorphine products on pediatric exposure and the findings addressed in the October 21, 2016, publication titled, “Pediatric Emergency Department Visits for Buprenorphine/Naloxone Ingestion – United States, 2008-2015;” and
 - d. The records reflecting the analysis of and views expressed by Scott R. Kegler, PhD, within the CDC’s Division of Research, Analysis, and Practice Integration, National Center for Injury Prevention and Control, regarding the impact of unit-dose packaging of buprenorphine products on pediatric exposure and the findings addressed in the October 21, 2016, publication titled, “Pediatric Emergency Department Visits for Buprenorphine/Naloxone Ingestion – United States, 2008-2015.”

It is **ORDERED** that counsel for Indivior shall forward the above-listed proposed subpoenas duces tecum to the Clerk’s Office for issuance. These subpoenas shall state that the items requested are to be returned to the Abingdon Clerk’s Office no sooner than 30 days from the date of issuance of the subpoenas. Upon return of any of the above documents or records to the Clerk’s Office, the

Clerk's Office shall notify all counsel that the documents or records are available for viewing.

The Motion is **DENIED** regarding the other subpoenas and/or items requested based on the court's finding that Indivior has not met the relevancy, admissibility and specificity requirements of *Nixon*. In particular, Indivior also seeks to subpoena certain records of the Drug Enforcement Administration, ("DEA"), SAMHSA and six various state agencies regarding seven different physicians, four of whom Indivior states are the four physicians identified in the Superseding Indictment as Doctors A-D. Indivior, however, has not provided the court with any information as to the identities of Doctors A-D or the relevance of the information sought from the other three physicians. The court also finds that the scope of information sought regarding each of these physicians does not meet the specificity requirement of *Nixon*.

The Clerk is directed to forward a copy of this Order to all counsel of record.

ENTERED: December 19, 2019.

/s/ Pamela Meade Sargent
UNITED STATES MAGISTRATE JUDGE